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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,556	09/14/2001	Brett P. Monia	RTS-0250	7962

7590 12/15/2003

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,556	MONIA ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Office action mailed August 26, 2003 is hereby vacated and finality of rejection of said vacated Office action is withdrawn. The instant Office action replaces said vacated Office action.

This Office Action is a response to Applicants Amendment filed November 10, 2003.

Claims 1, 2, 4-10, and 12-15 are pending in the instant application.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 15 was rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound 8 to 50 nucleotides in length that targets and inhibits the expression of fibroblast growth factor receptor 2 *in vitro*, does not reasonably provide enablement for a method of treating human having a disease or condition associated with fibroblast growth factor receptor 2 via a compound 8 to 50 nucleotides in length that targets and inhibits the expression of fibroblast growth factor receptor 2. **This rejection is withdrawn** in view of Applicants Amendment to claim 15 to recite, "A method of inhibiting the expression of fibroblast growth factor receptor 2 in cells or tissues comprising contacting said cells or tissues *in vitro* with the compound of claim 1 so that expression of fibroblast growth factor receptor 2 is inhibited".

Claim Rejections - 35 USC § 102

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Wilson, S. (GenEmbl Accession No. I32954). **This rejection is withdrawn** in view of Applicant's amendment to list specific nucleobase regions within the coding region of human fibroblast growth factor receptor 2 of SEQ ID NO: 3 that are to be targeted by antisense compounds, said regions not recited by Wilson, Accession No. I32954.

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Wilson, S. (GenEmbl Accession No. I87104). **This rejection is withdrawn** in view of Applicant's amendment to list specific nucleobase regions within the coding region of human fibroblast growth factor receptor 2 of SEQ ID NO: 3 that are to be targeted by antisense compounds, said regions not recited by Wilson, Accession No. I87104.

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al. (GenEmbl Accession No. AR090312). **This rejection is withdrawn** in view of Applicant's amendment to list specific nucleobase regions within the coding region of human fibroblast growth factor receptor 2 of SEQ ID NO: 3 that are to be targeted by antisense compounds, said regions not recited by Chenchik, Accession No. AR090312.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-10, and 12-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (Glia, 1999 Vol. 28:66-76), in further view of Baracchini et al. [U.S. Patent

No. 5801154] and Fritz et al. (Journal of Colloid and Interface Science, 1997 Vol. 195:272-288). **This rejection is withdrawn** in view of Applicant's amendment to list specific nucleobase regions within the coding region of human fibroblast growth factor receptor 2 of SEQ ID NO: 3 that are to be targeted by antisense compounds, said regions not recited by Yamada et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-10, and 12-15 are rejected under 35 U.S.C. 102(b) or 35 USC 103(a) as being anticipated by or obvious over Monia et al. [U.S. Patent No. 6,008,048]. **This is a new rejection.**

Monia et al. disclose an antisense oligonucleotide targeted to EGR-1 with the following sequence: 5'-tgggtgcaggctccaggg-3' (see SEQ ID NO: 17). This antisense oligonucleotide is reverse complementary to bases 1943-1954 of SEQ ID NO:3 of the instant invention. Since the

antisense oligonucleotide of Monia et al. meets all the structural requirements of the instant claims, the antisense oligonucleotide would also be expected to specifically hybridize to nucleic acid encoding human fibroblast growth factor receptor 2 as per applicant's definition set forth in the specification as filed, page 11, lines 30-37 and page 12, lines 1-26.

Furthermore, since the prior art antisense oligonucleotide meets all the structural limitations of the claims, the prior art antisense oligonucleotide would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, the instant invention is anticipated or obvious over Monia et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-10, and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The amendment filed November 10, 2003 introduces new matter into the disclosure because it recites the limitation, an antisense oligonucleotide 8 to 50 nucleobases in length targeted to nucleobases 1317 through 2720 of a coding region of a nucleic acid molecule encoding human fibroblast growth factor receptor 2 (SEQ ID NO:3) in claim 1. There is no support in the instant Specification as filed for an antisense oligonucleotide 8 to 50 nucleobases in length targeted to nucleobases 1317 through 2720 of a coding region of human fibroblast growth factor receptor 2 (SEQ ID NO:3). The response filed November 10, 2003 does not indicate where support can be found for the limitation an antisense oligonucleotide 8 to 50 nucleobases in length targeted to nucleobases 1317 through 2720 of a coding region of human fibroblast growth factor receptor 2 (SEQ ID NO:3). It is noted that Table 1 on pages 86-88, shows several dozen specific antisense oligonucleotide targeted to the coding region of a nucleic acid molecule encoding fibroblast growth factor receptor 2 (SEQ ID NO:3). However, Table 1 does not have support for an antisense oligonucleotide 8 to 50 nucleobases in length targeted to nucleobases 1317 through 2720 of a coding region of human fibroblast growth factor receptor 2 (SEQ ID NO:3) because there are gaps between the targeting regions within the coding region (see especially SEQ ID NO: 62 and 63). Therefore the limitation an antisense oligonucleotide 8

to 50 nucleobases in length targeted to nucleobases 1317 through 2720 of a coding region of human fibroblast growth factor receptor 2 (SEQ ID NO:3) is new matter.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06 which states, when filing an amendment, an applicant should show support in the original disclosure for new or amended claims (See MPEP § 714.02 and § 2163.06).

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-8693.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
December 1, 2003

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER